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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,471	02/27/2004	Robert J. D'Amato	05213-3001 (43170-295490)	8547

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EXAMINER	
BROOKS, KRISTIE LATRICE	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,471	D'AMATO ET AL.	
	Examiner	Art Unit	
	Kristie Brooks	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/7/04;8/24/04;9/20/04;11/19/04;12/12/05;7/24/06;8/14/06.

DETAILED ACTION

Status of Application

1. Claims 1-7 are pending and are presented for examination.

Drawings

2. Figure 3 of the drawings is objected to because it is not labeled "Figure 3." Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Method for Inhibition of Angiogenesis Utilizing Estrogenic Compounds."

4. The abstract of the disclosure is objected to as not being descriptive enough. The abstract should be within a range of 50-150 words and it should specify the compound (s) being utilized. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: The description of Figure 3 on page 3 needs to describe panel I, II and a, b, c, and d of panel II, each individually.

Appropriate correction is required.

6. The disclosure is objected to because of the following informalities: The heading for Example 4 on page 15 is included in the preceding paragraph instead of beginning on a new line.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diseases, such as angiogenesis, characterized by abnormal cell mitosis, it does not reasonably provide enablement for neovascularization not due to angiogenesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The claimed invention is a method of inhibiting neovascularization. According to the present specification, page 9, lines 8-10, the claimed compounds have anti-mitotic activity, which was "evaluated by testing their ability to inhibit the proliferation of new blood vessel cells (angiogenesis)". Angiogenesis is a process extending from neovascularization whereby blood vessels develop from pre-existing capillaries. The term "neovascularization" includes proliferation of blood vessels in tissue not normally containing them or the proliferation of blood vessels of a different kind than usual in a tissue; or the proliferation of blood vessels in abnormal tissue or in abnormal positions and encompasses different processes in the development of blood vessels other than angiogenesis, such vasculogenesis and arteriogenesis (see the attached articles, Franco, US 2002/0058612, see section 0005; Cao et al. (2005) **Update on therapeutic neovascularization.** *Cardiovascular Research*; Herron, US 2003/0175961; see sections 0103 and 0105; Campochiaro (2000) **Retinal and Choroidal Neovascularization**, *J. Cellular Physiology*; Cameliet (2003) **Angiogenesis in health and disease**, *Nature Medicine*; Lee et al. (1998) **Ocular Neovascularization: An Epidemiologic Review**, *Survey of Opthamology*), for example.

The present specification lacks examples of proliferation of blood vessels in tissues not normally containing them or of a different kind than usual in a tissue; or the proliferation of blood vessels in abnormal tissue or in abnormal positions. Moreover, the present specification lacks examples encompassing all the processes within neovascularization and thus, does not provide guidance to enable to the skilled artisan to practice the claimed invention commensurate in scope with the instant claims. The

skilled artisan would have to first search the literature for an assay that would encompass all aspects of neovascularization and would be useful in the determination of the ability of compounds to inhibit blood vessel proliferation in tissues not normally containing them or the proliferation of blood vessels of a different kind than usual in tissue. He would then have to test the numerous compounds encompassed by the claimed invention in said assays in order to determine the ability to inhibit blood vessel proliferation as defined by the term "neovascularization". Said determination would result in undue experimentation.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,908,910. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass inhibition of angiogenesis in a mammal. The instant invention differs from the cited patent by recitation of "inhibiting neovascularization" which includes inhibition of proliferation of blood vessels not encompassed by angiogenesis. Therefore, the method claimed in US Patent No. 6,908,910 is a species of the genus of the method encompassed by the instant claims, and as such it anticipates the instant invention.

11. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,109,187. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass inhibition of angiogenesis in a mammal. The instant invention differs from the cited patent by reciting specific mammalian diseases, i.e., treatment of specific mammalian diseases characterized by undesirable angiogenesis utilizing 2-methoxyestradiol. Therefore, the method claimed in US Patent No. 7,109,187 is a species of the genus of the method encompassed by the instant claims, and as such it anticipates the instant invention.

12. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,012,070.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass inhibition of angiogenesis in a mammal. The instant invention differs from the cited patent by reciting specific mammalian diseases, i.e., treatment of specific mammalian diseases characterized by undesirable angiogenesis utilizing 2-methoxyestradiol. Therefore, the method claimed in US Patent No. 7,012,070 is a species of the genus of the method encompassed by the instant claims, and as such it anticipates the instant invention.

13. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4,6, and 8 of U.S. Patent No. 5,661,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to treatment of mammalian diseases characterized by undesirable cell mitosis. The instant invention differs from the cited patent recitation of "inhibiting neovascularization" which includes inhibition of proliferation of blood vessels not encompassed by angiogenesis.

14. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,5, and 7 of U.S. Patent No. 5,504,074. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn o treatment of mammalian diseases characterized by undesirable angiogenesis. The instant invention differs from the cited patent recitation of "inhibiting neovascularization" which includes inhibition of

proliferation of blood vessels not encompassed by angiogenesis. Therefore, the method claimed in US Patent No. 5,504,074 is a species of the genus of the method encompassed by the instant claims, and as such it anticipates the instant invention.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 7:30am-5pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ANDREW WANG
SUPERVISORY PATENT EXAMINER